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A Novel Modified Laryngeal Mask Airway Allowing Full Separation of the Digestive and Respiratory Tracts, Along With Double-Catheter Ventilation, Diagnosis, and Treatment

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The aim of this study was to design a novel, modified, multifunctional, and safe laryngeal mask airway (LMA). We designed an LMA with an internal catheter extending beyond the tip of the cuff. The protruding end of the internal catheter was provided with a catheter cuff, the space between the internal and external catheters was ventilatory, and the inlet ends of the 2 catheters were provided with standard connectors. We found that this design prevented reflux or aspiration of gastric content into the airway, prevented LMA dislocation, allowed ventilation through both the internal and external catheters, and allowed endoscopic examination and treatment of the gastrointestinal and respiratory tracts through both the internal and external catheters. This design overcomes the drawbacks and extends the functions of previous LMAs, offering a new approach to the development of LMAs.

Key words: Laryngeal mask airway – Catheter – Ventilation – Design

Since the invention of the first laryngeal mask airway (LMA) in 1982, LMAs have been used worldwide for supraglottic airway management. Although LMAs have shown marked success in clinical anesthesia, the management of difficult airways, and emergency treatment, these devices also have disadvantages.[1–6] For example, an LMA cannot prevent stomach contents from refluxing into the respiratory tract and may move during surgery, affecting normal ventilation. In addition, an LMA may allow air leakage into the gastrointestinal tract during positive pressure ventilation, resulting in serious gastrointestinal distension and corresponding complications. Further, some patients may have difficulty positioning the LMA, thus requiring substitution of other ventilation devices. Finally,

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use of an LMA prevents an endoscope from entering the digestive tract for examination and treatment.

LMA-Combitube

To address these drawbacks, we have developed a new type of LMA, the LMA-Combitube (Fig. 1), which has been granted patent rights in China (patent No: ZL201020283210.3).

Here we describe the structure (Fig. 2) and the methods of application of the LMA-Combitube.

Structure

As shown in the structural diagram (Fig. 2), an LMA-Combitube consists of (1) an LMA cuff, (2) air holes, (3) an external catheter, (4) an LMA view cuff, (5) an internal catheter, (6) a catheter cuff, (7) a catheter view cuff, (8) a lateral hole, and (9) an X-ray imaging line.

Features

The unique structure of the LMA-Combitube has the following features:

1. The air chamber of the LMA cuff (1) communicates with the LMA view cuff (4) through a fine inflation line.
2. The air holes (2) on the inner surface of the LMA body communicate with the external catheter (3).
3. The external catheter (3) contains but does not communicate with the internal catheter (5), with the space between the external and internal catheters forming a ventilatory lumen.

Fig. 1 A picture of the LMA-Combitube.

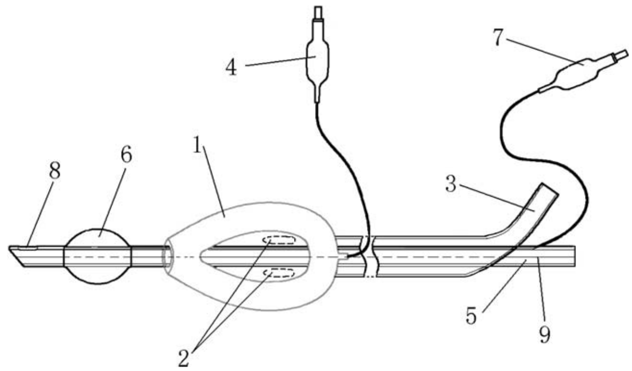

Fig. 2 Structural diagram of the LMA-Combitube: (1) an LMA cuff, (2) air holes, (3) an external catheter, (4) an LMA view cuff, (5) an internal catheter, (6) a catheter cuff, (7) a catheter view cuff, (8) a lateral hole, and (9) an X-ray imaging line.

4. The internal catheter (5) passes through the LMA cuff (1) and extends beyond its tip.
5. The protruding end of the internal catheter (5) is provided with the catheter cuff (6), and the air chamber of the catheter cuff communicates with the catheter view cuff (7) via the fine inflation line.
6. The lateral hole (8) is at the protruding end of the internal catheter (5), located on the wall distal to the catheter cuff (6).
7. The inlet ends of the external (3) and internal (5) catheters are provided with standard connectors, allowing a connection with the threaded pipes of anesthesia machines.
8. The X-ray imaging line (9) is located on the wall of the internal catheter (5).

Methods of application

Because of its structural features, the LMA-Combitube can be applied as follows:

1. Insertion of the protruding front end of the internal catheter into the esophagus followed by inflation of the catheter cuff will seal the space between the internal catheter and the esophagus, completely separating the digestive tract from the respiratory tract and preventing stomach contents from refluxing through the space into the airway.
2. Following insertion of the protruding front end of the internal catheter into the esophagus, a drainage or aspiration tube can be inserted through the internal catheter to drain or aspirate the stomach contents.

3. When the front end of the internal catheter is fully within the esophagus and the catheter cuff is inflated, the protruding front end of the internal catheter will be held in place within the esophagus, fixing the laryngeal mask in place and not allowing it to move if the patient's position is changed.
4. Both the external and internal catheters can be used for ventilation. When the front end of the internal catheter is fully within the esophagus, the air holes on the inner surface of the laryngeal mask body are situated opposite the glottis, allowing ventilation through the external catheter. If the front end of the internal catheter is within the trachea, ventilation can be performed through the internal catheter. This guarantees the safe use of the LMA-Combitube.
5. Inflation of the catheter cuff within the esophagus while positive pressure ventilation is carried out by the anesthesia machine will prevent gas leakage into the patient's digestive tract.
6. The gastrointestinal tract can be examined and treated by inserting an endoscope through the internal catheter; meanwhile, the external catheter is connected to ventilation equipment to control breathing, ensuring patient safety during examination and treatment procedures.
7. After determining that either the internal or external catheter is ventilated, an endoscope can be placed within the ventilated catheter for respiratory examination and treatment.
8. The presence of the X-ray line during radiography can help determine the specific location, depth, and distortion, if any, of the protruding end of the internal catheter within the patient, preventing accidents from occurring.
9. Before laryngeal mask placement, a bougie or gastric tube can be inserted through the internal catheter and passed through the mouth into the esophagus to provide guidance for accurate LMA positioning.
10. The wall at the protruding end of the internal catheter is provided with a lateral hole, through which ventilation or catheter placement can be performed when the protruding end is blocked.

Clinical applications

The effectiveness of the LMA-Combitube was successfully validated in a human patient simulator (Fig. 3).

Fig. 3 The effectiveness of the LMA-Combitube was proved in a human patient simulator.

The LMA-Combitube can be utilized in emergency procedures, clinical anesthesia, difficult airway management, and painless gastrointestinal and respiratory endoscopy, as described below.

Emergency treatment and difficult airway management

The LMA-Combitube can be implanted for laryngeal mask placement using a standard technique or, for more rapid placement, using improved techniques. When an LMA-Combitube is inserted into a patient's throat and cannot advance any further, the LMA and catheter cuffs can be inflated using the LMA view and catheter view cuffs, respectively, and the artificial ventilation equipment can be connected to the internal and external catheters (Figs. 4 and 5). By auscultation or measurement of end-tidal carbon dioxide ($Petco_2$), the ventilated catheter of the two can be determined, whose connector will be linked to the ventilation equipment to control breathing. This allows the airways to be opened in a timely manner, to control breathing and to rapidly overcome difficult airways.

Clinical anesthesia

Following induction of anesthesia or full surface anesthesia of the throat, the LMA-Combitube can be implanted for laryngeal mask placement or for guided placement of an anesthesia laryngoscope or fiberoptic bronchoscope. Alternatively, a bougie or gastric tube can be inserted into the internal catheter, from the mouth into the esophagus, with the front end of the internal catheter guided to fully

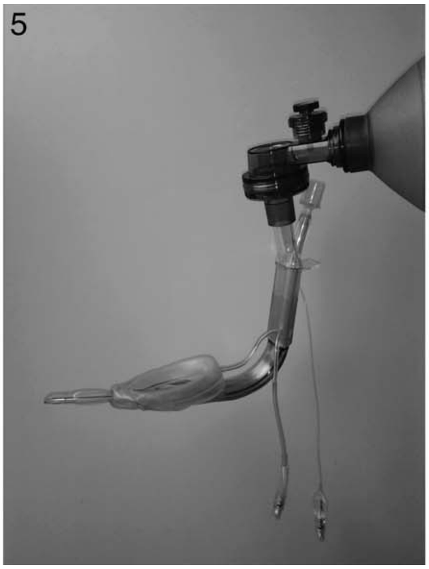

Fig. 4 The artificial ventilation device is connected to the internal catheter.

Fig. 5 The artificial ventilation device is connected to the external catheter.

Fig. 6 An endoscope can enter the esophagus via the internal catheter when the artificial ventilation device is connected to the external catheter.

enter the esophagus. When the LMA-Combitube cannot be advanced any further, the LMA and catheter cuffs can be inflated through the LMA and catheter view cuffs, respectively, and the threaded pipe of the anesthesia machine can be connected to the external catheter for ventilation. If surgical operations are obstructed by a full stomach or a gas-bloated stomach, a drainage tube or aspiration catheter can be placed through the internal catheter to drain or aspirate the gastric contents. If the front end of the internal catheter is found to be in a patient's trachea, the catheter cuff can be inflated through the catheter view cuff and the threaded pipe of the anesthesia machine can be connected to the internal catheter, resulting in ventilation through the internal catheter.

Painless gastrointestinal endoscopy

After induction of anesthesia, the LMA-Combitube can be implanted in spontaneously breathing patients. After making sure that the patient can be ventilated through the external catheter and that the internal catheter has entered the esophagus, the artificial ventilation device can be connected to the external catheter, allowing assisted breathing. Insertion of an endoscope through the internal catheter can allow procedures such as gastroscopy, retrograde cholangiopancreatography for stone removal, and stent implantation to be performed under inhalation or intravenous anesthesia (Fig. 6).

Painless respiratory endoscopy

Following induction of anesthesia, the LMA-Combitube is implanted. After ensuring that the patient can be ventilated through either the external or internal catheter, an endoscope can be inserted into the ventilated catheter, allowing respiratory examination and treatment (Figs. 7 and 8).

Conclusions

The unique design of the LMA-Combitube overcomes the drawbacks and extends the functions of conventional LMAs. The LMA-Combitube can completely insulate the digestive tract from the respiratory tract, preventing reflux and aspiration of gastric content. The internal catheter can provide guidance for accurate positioning of the LMA-Combitube and secure it from dislocation. Both the internal and external catheters can allow ventilation and thus overcome difficult airways in a rapid manner. The digestive and respiratory tracts can be endoscopically examined through internal and

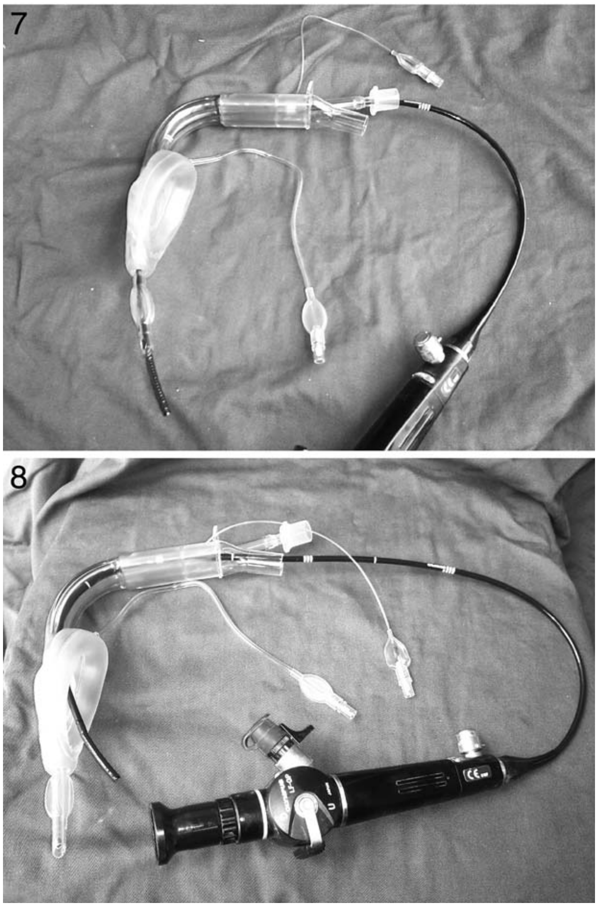

Fig. 7 An endoscope can enter the respiratory tract via the internal catheter when the internal catheter is ventilated.
Fig. 8 An endoscope can enter the respiratory tract via the external catheter when the external catheter is ventilated.

external catheters. Thus, this new device represents an advance in the development of LMAs.

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